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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT	PAPER NUMBER
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1742

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,401

Applicant(s)

ABRAMS ET AL.

Examiner

George P. Wyszomierski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-60 is/are pending in the application.
- 4a) Of the above claim(s) 57-60 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-41 is/are allowed.
- 6) ☒ Claim(s) 33-36 and 42-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. Newly submitted claims 57-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are directed to a method for making an elongated tubular member from a NiTi alloy, and would have been the subject of a restriction requirement had they been present in the application at the time of the previous Office Action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The terminal disclaimer filed on November 29, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patents 5,341,818, 5,411,476, 6,280,539, 6,461,453, 6,638,372 and 6,682,608 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. The examiner agrees with Applicant that the subject matter of instant claims 33-37 is entitled to a priority date of December 18, 1990, the filing date of Application serial no. 07/629,381. The examiner further submits that new claims 42, 43, 45, and 48-56 are entitled to that same priority date. Instant claims 38-41, 44, 46 and 47 are entitled to a priority date of December 22, 1992, the filing date of Application serial no.

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07/994,679, as the '679 application was the first disclosure by Applicant of an alloy containing platinum or palladium.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 43, 45, 51, 53 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Jervis (U.S. Patent 4,665,906).

Jervis discloses a Ni-Ti-V alloy, displaying stress induced martensite at 35-40 degrees C (Jervis column 4, lines 10-12), and exhibiting up to 5% recoverable strain (Jervis column 3, line 51). This alloy is made into products such as catheters and cannulas (Jervis example 2), which the examiner takes to be the full patentable equivalent of an “elongated tubular member for use in a body lumen”. With respect to claim 53, whichever portion of the Jervis material one designates as the “distal portion” comprises the alloy mentioned supra. Thus, all aspects of the claimed invention are held to be fully disclosed by Jervis.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 49, 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jervis.

Jervis, discussed in item no. 5 supra, does not disclose the specific stress levels which result in phase transformation as defined in claims 49 and 50, and does not specify a member with only a portion formed from a NiTi alloy as defined in claim 52. These differences are not seen as resulting in a patentable distinction between the prior art and the claimed invention because:

a) Given that the material of Jervis may be the same as that used in the present invention, it is a reasonable assumption that its properties, such as transformation stress level, would likewise be the same in either the prior art or the present claims.

b) With respect to claim 52, the examiner's position is that the Jervis disclosure encompasses products in which any and all portions, or any subset of portions, are made of the material as disclosed in that reference.

Thus, a prima facie case of obviousness is established between the disclosure of Jervis and the presently claimed invention.

8. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jervis, as above, in view of Sugita (U.S. patent 4,969,890).

The Jervis patent does not specify a proximal portion coated with a polymeric material as set forth in the instant claims. Sugita, particularly column 3, lines 20-24 therein, indicates that it was known in the art, at the time of the invention, to include a polymeric coating upon a NiTi alloy which is to be used as part of a catheter, i.e. for the same purpose as the materials of Jervis.

Therefore, the combined disclosures of Jervis and Sugita would have rendered a product constructed as defined in the instant claims obvious to one of ordinary skill in the art.

9. Claims 33-36 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jervis, as set forth supra, in view of either Fountain et al. (U.S. Patent 4,310,354) or Simpson et al. (U.S. patent 4,631,094).

Jervis discloses medical devices, such as catheters and cannulas, made preferably of a nickel-titanium shape memory alloy which is in a stable austenite phase under ambient conditions, which transforms to martensite upon the application of stress, and has a recoverable strain of up to 5%.

Jervis does not specify the process steps, referred to in product-by-process terms in the instant claims, does not specify the transformation stress recited in instant claims 34 and 35, does not specify the outer diameter and wall thickness as defined in instant claim 36, and does not specify the ternary element of instant claim 33. However,

a) With regard to the process steps, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art. See *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524).

b) With respect to the transformation stress, because the material used in the prior art and the claimed invention is the same (superelastic Ni-Ti alloy), it is a reasonable assumption that its properties (such as transformation stress) would likewise be the same in either the prior art or the claimed invention.

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c) With respect to size of the products, both the prior art materials and those as claimed are intended for use in blood vessels in the human body, and the proper size for such materials would be dictated by constraints associated with natural limitations imposed by the size of those blood vessels. These constraints would be identical in the prior art and the claimed invention.

d) The Fountain and Simpson patents indicate that it was well-known in the art, at the time of the invention, to include a non-zero amount of a third element such as cobalt, chromium, iron or copper in Ni-Ti shape memory alloys. See, for instance, Fountain column 2, lines 43-46 or Simpson column 6, lines 44-48.

Thus, the disclosure of Jervis, together with the third element teachings of Fountain or Simpson et al., would have taught the presently claimed invention to one of ordinary skill in the art.

10. Claims 43-53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fountain et al. in view of Dotter (U.S. patent 4,503,569) or Sugita.

Claims 43-45, 48-53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of Dotter or Sugita.

The Fountain and Simpson patents disclose superelastic NiTi alloys containing one or more of the ternary or higher elements as set forth in the instant claims; see Fountain column 2, lines 43-46 or Simpson column 6, lines 44-48. With regard to claims 45, 49, 50 and 56, while Fountain and Simpson do not recite the properties as set forth in the instant claims, it is a reasonable assumption that the alloys of the prior art, being of the same composition as those claimed, would in fact possess the same properties as well.

Fountain and Simpson do not disclose these materials in the form of an "elongated tubular member" as required by the instant claims. Dotter and Sugita indicate that it was

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conventional in the art, at the time of the invention, to form superelastic NiTi alloys into the form of elongated tubular members. With regard to instant claims 51-53, the examiner's position is that the Dotter and Sugita patents encompass products in which any and all portions, or any subset of portions, are made of the material as disclosed in those references.

Thus, the combination of Fountain or Simpson et al., together with the tubular configuration disclosure of Dotter or Sugita, would have taught a product as presently claimed to one of ordinary skill in the art.

11. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fountain et al. or Simpson et al., either of which in view of Sugita.

In addition to the teachings of Fountain, Simpson, and Sugita as set forth in item no. 10 supra, the Sugita patent indicates that it was conventional in the art to include a coating such as a polymeric coating upon NiTi alloys; see Sugita column 3, lines 20-24. This teaching of Sugita would have motivated one of skill in the art to include such a coating upon the products made by combining Fountain or Simpson with Sugita in the manner as set forth in item 10 supra.

12. Claims 43-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 5,318,527.

Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims of the '527 patent require structural details not recited in the instant claims, both the present claims and the '527 claims are directed to elongated materials suitable for insertion into a human blood vessel and made of a NiTi alloy containing certain ternary element(s) in a given amount. These

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alloys, being of the same composition in both sets of claims, would be expected to have the same properties as recited in the instant claims. Particularly, it would appear that practicing an invention in accord with '527 claim 36 would involve practicing an invention in accord with the instant claims.

Thus, no distinction is seen between the products as defined in the instant claims and those set forth in the claims of the '527 patent.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. In a response filed November 29, 2005, Applicant has provided Terminal Disclaimers with respect to several prior patents. These disclaimers are accepted as stated in item no. 2 supra. The examiner further agrees that a Disclaimer is not necessary with respect to U.S. patent 6,419,693, as the claims of that patent do not disclose or suggest the use of titanium as required by all of the instant claims. The

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examiner also agrees that the previously cited Kugo and Schwartz patents are not prior art to the present invention, for reasons as stated in item no. 3 supra.

With regard to the prior art, Applicant alleges that the Jervis patent should not be applied against claims 33-36 because Jervis does not disclose the ternary element of the instant claims. However, the examiner believes that the combined disclosure of Jervis together with that of Fountain or Simpson would have taught the claimed invention to one of skill in the art, for reasons as set forth in item no. 9 supra.

15. Claims 37-41 are allowable over the prior art of record. The prior art does not disclose or suggest tubular bodies made of a cold worked alloy of titanium, nickel, cobalt and chromium, as defined in the instant claims.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the new central facsimile number, (571)-273-8300. This new Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE WYSZOMIERSKI
PRIMARY EXAMINER
GROUP 1742

GPW
February 13, 2006